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UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

HANSEN BEVERAGE COMPANY, a Delaware corporation, Plaintiff, v. INNOVATION VENTURES, LLC dba LIVING ESSENTIALS, a Michigan corporation, Defendant.	CASE NO. 08-CV-1166 IEG (POR) **HANSEN BEVERAGE COMPANY'S REPLY TO LIVING ESSENTIALS' OPPOSITION TO ITS MOTION FOR PRELIMINARY INJUNCTION** Date: September 15, 2008 Time: 10:30 a.m. Courtroom: 1 Hon. Irma E. Gonzalez

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I
INTRODUCTION

Living Essentials' opposition mirrors its *5-hour Energy*® labels and ads—plausible at first; but, after review, misleading, and, in part, literally false. The core of Living Essentials' opposition is Mahady's declaration and Blum's "clinical study." Mahady's declaration, however, is riddled with demonstrably false statements and Blum's "clinical study," a materially altered version of which Living Essentials submitted to the Court, is a sham. With or without Mahady and Blum, Living Essentials still cannot overcome either the fact that its *5-hour Energy*® name, labels and ads are literally false and the consequence that flows from that fact—an injunction.

II
THE FOUNDATION OF LIVING ESSENTIALS' OPPOSITION CRUMBLES

Living Essentials pins its hopes on Mahady and Blum. Tested by facts, both fail.

Mahady's Declaration Has Patently Verifiable False Statements.

Living Essentials uses Mahady's second-hand declaration to baptize Blum's "clinical trial." The Court, however, does not have to wade through who has "better" science. Instead, if the Court compares but a few of Mahady's sworn statements with readily available, verifiable facts, the Court will see that the whole Mahady enterprise fails.

Mahady's Statement.

Mahady declared: "The Blum clinical trial of 5-hour ENERGY® was performed by Dr. James Blum, who **is** an Epidemiologist and Biostatistician **at the University of New England Medical School**."[1]

The Facts.

Mahady's statement sounds impressive. Blum, however, is **not** on the faculty of the University of New England. The University of New England **does not have** a "Medical School."[2]

Mahady's Next Statement.

"**Approval** to perform this study was obtained from the **Institutional Review Board** of

[1] Mahady declaration, ¶ 8, emphasis added.
[2] Morrison declaration, ¶¶ 3 and 4.

the **University of New England Medical School**."[3]

The Fact.

Approval from a noted medical school's IRB adds luster to Blum's "clinical trial," to say nothing of implied *imprimatur*. The IRB of the University of New England, however, **never approved** Blum's "clinical trial."[4] The import of this misstatement may be greater than its fraud on the Court. A clinical trial on human subjects **without** prior IRB approval may be illegal.[5]

Another Mahady Statement.

"The clinical site was located at the **Southern Maine Research Center** (**independent medical research center**) located at **344 Cumberland Street, Westbrook, Maine**."

The Facts.

An "independent medical research center" with a prestigious-sounding name puts icing on Blum's cake. 344 Cumberland Street in Westbrook, however, houses Richard Stockwell's **Maine Proctology Center**. Further research on Dr. Stockwell, D.O. reveals: "complete office-based proctology including painless hemorrhoid care, laser and infrared technology, minimally invasive office surgery, high resolution anoscopy, condyloma(warts), cancer screening and prevention and constipation/pelvic floor dysfunction. In Business Since 1998."

Under the Maine Proctology Center name are the words, "Southern Maine Research Center," but an office visit reveals that 344 Cumberland Street is just a doctor's office in a semi-rural suburb of Portland.[6] There is **no record whatsoever** of any "independent medical research center" called "Southern Maine Research Center;" a Maine registry search on the business produced nothing.[7] Anyone can paint a name on a sign, but a sign does not an "independent medical research center" make.

Conclusions.

Did Dr. Mahady deliberately lie? That the Court can decide. Does it mean that Mahady made sworn statements without checking fundamental facts? Absolutely. Does it mean that Mahady was willing—intending this Court to rely on her—to swear to anything Living Essentials put in front of her? Obviously. Does it mean that this Court can disregard the whole Mahady declaration as fundamentally untrustworthy? Certainly.[8]

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[3] Mahady declaration, at ¶ 8.
[4] *Id*. at ¶¶ 3 and 5.
[5] 45 C.F.R. §§ 46.101; 46.107 and 46.109.
[6] Donnally declaration, ¶¶ 4-8.
[7] *Id*. at ¶ 9.

Hansen could dissect Mahady's declaration, clause by clause; given her sworn misstatements, however, that exercise is unnecessary. But two points bear mention.

Mahady criticizes Hansen's expert because—she repeatedly asserts—he did not have access to Blum's "clinical trial." Mahady is wrong—again. She apparently does not know that Blum's "confidential" "study" is online. Hansen had it before Living Essentials produced it.[9] Ignorance, however, is no excuse for swearing to a "fact" if she did not know if it was true or not.

Mahady says 24% of *5-hour Energy®* users in the "clinical study" experienced a "crash." That is bad enough and demonstrates literal falsity. Mahady, however, misreads the report. The "Notes on the Crash" paragraph states that 24% of the 5-Hour users experienced a "Moderately-SEVERE crash." The Table states that 5-Hour users crashed 2.43 hours after reaching their peak energy level.[10] In short, **almost all** of them necessarily experienced a crash, not just 24%.

Her misinterpretation notwithstanding, Mahady **still** concludes that the "clinical study" **supports** the unqualified "**no** crash" claim.[11] If Pfizer promoted a drug with "no side effects," when its **own** clinical study demonstrated that at least 24% of users suffered a specific side effect, no credible expert would tell a court that the drug has **zero** side effects. But Mahady does. Any support she **might** have provided just crumbled.

Living Essentials Has Given the Court an *Altered* Version of the Blum Report.

Living Essentials' use of Blum's May 11, 2007 "Final Report" is at best disingenuous; worse, a fraud on the Court. Living Essentials did not tell the Court about the online version of

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8 *U.S. v. Chaplin*, 54 F. Supp. 682, 687 (S.D. Cal. 1944) ("A witness false in one part of his testimony is to be distrusted in others."); *Hamilton et al. v. Williams*, 2006 U.S. Dist. LEXIS 17134, *19 (E.D. Cal. 2006) ("[W]here a person learns one representation is false, he may not assume other representations are true.")

9 Kammer declaration, ¶¶ 2-7. The self-promoting Dr. Blum was seemingly more interested in publicity than any promised confidentiality—and sloppy as well.

10 Kammer declaration, Exhibit 1, p. 24.

11 Mahady declaration, ¶ 4.

Blum's report—perhaps because the "sealed" version it gave the Court has been **altered by deletion** in several critical respects from the version Blum published online.

For example, the online report mandates randomized metabolic testing.[12] The Court will search in vain, however, for any reference to metabolic testing in its version. Such metabolic testing is not only important; its absence, suspicious.[13] The online report also mandates specific chi-square testing and regression analysis.[14] These, however, are not included in what Living Essentials gave the Court. Their absence jeopardizes any reliability.[15]

Hansen also asks the Court to review Blum's claimed credentials and IRB approval in the version Living Essentials filed and compare them to Dr. Morrison's declaration about both Blum's claimed credentials and no IRB approval and to Donnelly's declaration about the Cumberland Street address.

Living Essentials' filing an altered version of the May 11, 2007 "Final Report" under seal—without acknowledging the online version or that it had submitted an altered version—is grounds, at a minimum, for this Court to disregard Blum's report *in toto*. But there is more.

Blum's Sham "Clinical Study."

Living Essentials has at least three energy drink products, each with different ingredients.[16] Hansen has several Monster Energy® drink products, also with different ingredients.[17] Neither Blum, however, nor Mahady nor Living Essentials tells the Court **which** Living Essentials' product Blum says he compared to **which** Hansen product. This failure is not only less than forthright with this Court but it alone invalidates Blum's effort.

Living Essentials had Blum conduct his "clinical trial" 3 years ***after*** *5-hour Energy*® went on the market to answer an NAD investigation;[18] the "results" had to "fit" its *5-hour Energy*® advertising claims. Even at that, Blum's "results" do not corroborate Living Essentials' false claims.[19] However if this Court views this single "clinical trial"—only 42 participants, 40% of whom already used energy drinks (hence, bias) and who were told in advance what to expect (inevitable bias)— the flaws of which are obvious,[20] the results **hurt**, not help, Living Essentials. Fewer than 60% of subjects using *5-hour Energy*® claimed **any** "energy" that lasted for 5 hours; 24% experienced a moderate to severe "crash;" almost **all** "crashed" to some extent.[21]

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[12] Pages 3 and 27. "Those randomized for metabolic testing will have their initial metabolic test during the morning session;" "Since we need the subjects at the Clinic in the morning for the metabolic testing, all visits must be in the morning;" "There were several categories that did not show any differences between the drinks … metabolic rates."

[13] Davis declaration, ¶ 3.

[14] Pages 6 and 7. "Regression models will be fitted using weight as a continuous variable and as a categorical outcome marker to determine if there are any additional confounders to report. These modes will be helpful in explaining the results if any of the baseline characteristics are either clinically or statistically different."

[15] Davis declaration, ¶¶ 4-6.

[16] Sacks declaration, ¶ 2.

[17] *Id.* at ¶ 4.

The National Advertising Division Investigation.

Living Essentials touts the NAD investigation; it is hard to understand why. [22] Even if NAD had conducted a proper investigation and analyzed Living Essentials' "clinical trial," it would be irrelevant. In *McNeil-PPC*,[23] the American Dental Association—an independent entity, not just a trade group—approved Listerine's advertising claims that it worked "as well as floss." That notwithstanding, because the statement was literally false, the court enjoined the commercial. Living Essentials cannot hide behind NAD's findings.

If, however, one considers the NAD report, it **hurts** Living Essentials' position. **First**, NAD stated the obvious—"this study [from Blum's "clinical trial"]did not support [Living Essentials] unqualified claims that 5-hour Energy results in "no" crash effect."[24] NAD told Living Essentials to stop its "no crash" claim. Living Essentials still has not. **Next,** Living Essentials was able to fool NAD on all its claims—including the **5-hour duration—**because none of its

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[18] National Advertising Division of the Better Business Bureau.

[19] Any "clinical trial" a manufacturer buys to ward off a false claims investigation where the "clinical trial" is designed to prove claims of a manufacturer's golden egg that has already been on the market for years is inherently skewed, especially where the provenance of the "clinical trial" is itself suspect—false statements about the credentials of the "lead investigator," about medical school IRB approval and about the "independent medical research center" that supposedly performed the "clinical trial."

[20] Davis declaration, ¶ 2.

[21] See p. 3, above.

[22] NAD is the advertising industry's self-regulating arm. News Release p. 1 Exh. B to Henderson Declaration., Docket No. 25, Attachment No. 22. NAD targeted *5-hour Energy*® and investigated nine advertising claims, some at issue here: "Drink it in seconds. Feel it in minutes. Lasts for hours;" "Hours of energy now. No crash later – and no jitters;" "Just one quick drink and you'll get hours of energy for work, play and everything in between." Living Essentials tried to justify the specific advertising claims at issue.

[23] *McNeil-PPC, Inc. v. Pfizer Inc.*, 351 F.Supp.2d 226 (S.D.N.Y. 2005).

[24] NAD Report, p. 11, Exh. A to Henderson Declaration, Docket No. 26.

"evidence" was tested in the "crucible of cross-examination."[25] NAD accepted Living Essentials' "evidence"—including what NAD believed was a valid "placebo controlled, randomized clinical trial." The study, however, was not "placebo controlled," was not "clinical," nor was Blum a medical school professor. Again, after NAD found that Living Essentials' failure to give the caffeine content on *5-hour Energy*® bottles caused consumer confusion, Living Essentials assured NAD last year that it "intends to modify its advertising to accommodate." It has not, demonstrating yet again that Living Essentials will say anything—to NAD, this Court or the public to get out of a bind.

III
LIVING ESSENTIALS CANNOT GET AROUND ITS LITERALLY FALSE ADS

To justify itself, Living Essentials' has to ignore that its own "clinical trial" disproves its "no crash later" claim for *5-hour Energy*®. Even NAD found this claim false.

Next, Living Essentials defends its *5-hour Energy*® claim, its own admission that the product provides no physical energy notwithstanding. To pull that off, however, it has to engage in the tortured attempt to redefine "energy." It turns to the **third** definition in an unpublished, online dictionary—Wordsmythe Dictionary—to come up with synonyms "vigor, liveliness and vitality." With these newly-found definitions, it explains, its advertising could be **construed** as true since, it says, *5-hour Energy*® improves mood and increases vigor.

Living Essentials, however, simply ignores the **context** of its own advertising—from the "action scenes" in its commercials to the prominent picture of the runner on the bottle soaring up the mountain.[26] All suggest that the **energy** in its name and to which it constantly refers is none other than **physical energy**. "A literally false message may be either explicit or conveyed by necessary implication when, considering the advertisement in its entirety, the audience would recognize the claim as readily as if it had been explicitly stated."[27] "Vigor" and "vitality" do not give a runner strength or energy to run up a mountain. Its claim to the contrary is disingenuous.

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[25] *Crawford v. Washington*, 541 U.S. 36, 61 (2004). Hansen has and will continue vigorously to do so here.

[26] The case law, however, mandates that **context** is critical. *Southland Sod Farms v. Stover Seed Co.*, 108 F.3d 1134, 1139 (9th Cir. 1997).

[27] *Scotts Co. v. United Indus. Corp.*, 315 F.3d 264, 274 (4th Cir. 2002).

Living Essentials points to Hansen's ads that one of its low calorie products provides an "energy boost." It is, however, the glucose in those products that provides energy and Hansen never claims a **duration** for the "energy boost" as Living Essentials does for *5-hour Energy*®.[28]

Even Mahady undercuts Living Essentials. She gives four definitions of energy, all of which support Hansen (and indisputable science) that energy necessarily means physical energy: "1. The **power** by which anything acts effectively **to move** or change...;" "2. Habitual tendency to and readiness for effective **action**;" "3. **Power in active exercise**; force in operation;" and "4. Physics: The **capacity of doing work** and overcoming inertia...."[29] Mahady herself agrees that feelings of "good mood" and "vitality" do not constitute energy.

Indeed, were Living Essentials honest, it would call its product "Vigor" or "Vital" or some such. It would also kill the "5-hour" claim—literally false precisely because of the **duration** it asserts. If Bausch and Lomb advertised "once-a-week" disposable contact lenses that, in fact, needed replacing after four days, that would be false advertising. So too here.

IV
LITERALLY FALSE CASES DO NOT APPLY THE TRADITIONAL FOUR- FACTOR INJUNCTIVE RELIEF TEST

Living Essentials refuses to acknowledge the cases that state unequivocally that **irreparable harm is presumed** when a competitor's advertisement is literally false. Just two months ago, the Central District of California in *Pom WonderFul,*[30] granted a preliminary injunction in a literal falsity case, **without** plaintiff's having to "introduce consumer testimony, marketing surveys or *proof of lost profits*"[31] Living Essentials does not even mention this case.

Living Essentials also ignores *Time Warner Cable*[32] and *Castrol*[33] —each holding that irreparable harm is presumed. Instead, it says that *eBay*[34] has done away with that presumption. *eBay*, however, did no such thing. *eBay* was **not** a literal falsity case; *eBay* was a **patent case** that appropriately applied the traditional four-factor test. This distinction is critical, precisely because literal falsity cases **presume** irreparable harm and, as a consequence, do not apply the traditional factors. *eBay* did not limit the holdings of *Time Warner Cable* and *Castrol* and, Living Essentials' assertion that it does is, once more, less than forthright.

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[28] Sacks declaration, ¶ 7.
[29] Mahady declaration, ¶ 12.
[30] *Pom Wonderful, LLC v. Purely Juice Inc.*, 2008 U.S. Dist. LEXIS 55426 (July 17, 2008) (Snyder, J.)
[31] *Id.* at *30.
[32] *Time Warner Cable, Inc. v. Directv*, Inc., 497 F.3d 144, 158 (2d Cir. 2007).
[33] *Castrol Inc. v. Pennzoil Co.*, 987 F.2d 939, 944 (3d Cir. 1993).
[34] *eBay v. MercExchange, LLC*, 547 U.S. 388 (2007).

Living Essentials' reliance on *Reno Air Racing Ass'n.*,[35] *MyGym, LLC*[36]and *Harris Research, Inc.*[37] is equally misplaced; all involved **trademark** infringement. None had anything to do with the presumptions that go along with literal falsity cases.[38]

Living Essentials also argues that *Castrol* and *Time Warner Cable* do not apply because they only allow for the irreparable harm presumption when one competitor mentions the other competitor's product by name. Wrong, again—on the facts and the law.

First, Living Essentials compares itself with Hansen's Monster Energy® drinks—on its website, in its commercials, and even in its "clinical trial" posted on the Internet. Comparative advertising exists here—in spades.[39] More importantly, the commercials in *Castrol* and *Time Warner Cable* ***did not*** identify their competitor by name.

Castrol sued Pennzoil because it "claimed that its product 'outperforms any leading motor oil against viscosity breakdown'" and that "Pennzoil's motor oil provides 'longer engine life and better engine protection.'"[40] No ad mentioned Castrol's product by name. Yet, the court issued a preliminary injunction and the Third Circuit affirmed. Here, Living Essentials' commercials directly attack Hansen whose products contain sugar, caffeine and guarana. By falsely[41] suggesting that *5-hour Energy*® does not have any of those ingredients, it claims to be a superior energy drink—just as Pennzoil did in *Castrol*. Living Essentials' failure specifically to mention Hansen is immaterial.

Likewise in *Time Warner Cable*, DIRECTV never mentioned its competitor by name; it

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35 *Reno Air Racing Ass'n. Inc. v. McCord*, 452 F.3d 1126 (9th Cir. 2006)

36 *MyGym LLC v. Engle*, 2006 WL 3524474 11 (D. Utah 2007).

37 *Harris Research v. Lydon*, 505 F.Supp.2d 1161 (D. Utah 2007).

38 It is apparent Living Essentials simply Shepardized the *eBay* case for Lanham Act cases without determining if the facts and reasoning of those cases apply.

39 Sacks' declaration, ¶¶ 5 and 6.

40 *Castrol Inc.* at 940. For an extended discussion of these cases, see Hansen's opening brief at pp. 21-23.

41 *5-hour Energy*® contains caffeine.

simply referred to the generic "cable." In another commercial, the narrator states "For an HD picture that can't be beat, get DIRECTV"—even the word "cable" was not used. The court still found the commercials literally false and granted Time Warner a preliminary injunction.

Living Essentials does not bother to address *McNeil-PPC v. Pfizer*,[42] in which Pfizer touted Listerine to be "as effective as floss." The court found this claim literally false, found that McNeil-PPC had been irreparably harmed, and issued a preliminary injunction. Like Hansen, McNeil-PPC was **not** the only floss manufacturer, but one of several, a "market leader" like Hansen—sufficient, nonetheless, for the court to presume irreparable injury as a matter of law.

The rationale for injunctions in literal falsity cases is **not** based on a direct attack on a competitor. Rather, literally false advertisements harm competitors in that industry; hence the presumption. Living Essentials' assertion that the Court must separate each commercial, label and online comparison, and analyze each independently to determine the amount of harm both ignores the case law and misses the point why its literally false ads presume irreparable harm.

Hansen's Sales Are Irrelevant.

Living Essentials' attempt at calculating the "absence" of irreparable harm by looking at Hansen's sales figures is mere slight-of-hand. **First**, because literal falsity presumes irreparable harm, Hansen's sales record is immaterial. **Second**, Hansen's strong sales figures could be the result of many business factors, none of which relate to Living Essentials' conduct, including, a larger advertising budget, new markets, new products and improved distributor relationships. Therefore, Living Essentials' argument that Hansen has not been harmed by its false advertisement is pure speculation. It is impossible to know what Hansen's sales would have been absent Living Essentials' false claims. "Because it is virtually impossible to prove that so much of one's sales will be lost or that one's goodwill will be damaged as a direct result of a competitor's advertisement, the plaintiff **need not point to an actual loss or diversion of sales** to satisfy this requirement."[43]

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[42] *McNeil-PPC, Inc. v. Pfizer Inc.*, 351 F.Supp.2d 226 (S.D.N.Y. 2005).

[43] *Time Warner Cable, Inc.*, *supra, at* 161, citing to *Coca-Cola Co. v. Tropicana Prods., Inc.*, 690 F.2d 312, 316 (2d Cir. 1982). Emphasis added. *See also McNeil-PPC, supra*, at 250.

Hansen Moved Promptly After Discovering Living Essentials' False Advertising.

Perhaps Living Essentials intends the third time to be a charm. Yet again it argues that Hansen should have sued it sooner. Living Essentials still gets it wrong. Living Essentials raised this precise—and error-laden—claim in its *ex parte* applications both to this Court for delay[44] and Judge Porter for expedited discovery.[45] Hansen addressed this issue with **facts** that set the record straight.[46] Hansen will not waste the Court's time reiterating what it has already said. Instead it respectfully refers the Court to the facts in the Sacks declarations and the argument in its earlier briefs. That timeline shows the "delay" claim is one more red herring.

Living Essentials' Hardship is Immaterial.

Living Essentials again ignores the cases that hold irreparable harm is **presumed** in literal falsity cases, eliminating the need to balance hardships. Predictably, none of the cases it cites are literal falsity cases; hence, inapposite. As Living Essentials argued in the Michigan district court, stripping away labels and a name is a consequence of Lanham Act violations.[47]

V
CONCLUSION

Living Essentials' "evidence" that its product actually does what it claims fails. *5-hour Energy's®* advertising is literally false and, as the case law mandates, it should be enjoined.

DATED: September 8, 2008

Respectfully submitted,

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44 Docket no. 11, p. 6.
45 Docket no. 12, pp. 6-7.
46 Docket no. 16, pp. 9-10. See especially Sacks' Declaration, ¶¶ 4-6 (Attachment No. 2).
47 See discussion of *Innovation Ventures v. N2G Dist.* in Hansen's opening brief, pp. 6 and 24 (Docket No. 7).

CERTIFICATE OF SERVICE

I caused the **HANSEN BEVERAGE COMPANY'S REPLY TO LIVING ESSENTIALS' OPPOSITION TO ITS MOTION FOR PRELIMINARY INJUNCTION** to be served in the following manner:

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Manual Notice List

The following is the list of attorneys who are not on the list to receive e–mail notices for this case (who therefore require manual noticing).

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UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

HANSEN BEVERAGE COMPANY, a Delaware corporation, Plaintiff, v. INNOVATION VENTURES, LLC dba LIVING ESSENTIALS, a Michigan corporation, Defendant.	CASE NO. 08-CV-1166 IEG (POR) **HANSEN BEVERAGE COMPANY'S OBJECTIONS TO THE DECLARATION OF GAIL MAHADY FILED IN SUPPORT OF LIVING ESSENTIALS' OPPOSITION TO THE MOTION FOR PRELIMINARY INJUNCTION** Date: September 15, 2008 Time: 10:30 a.m. Courtroom: 1 Hon. Irma E. Gonzalez

Hansen Beverage Company objects to the following evidence submitted by Innovation Ventures, LLC dba Living Essentials in support of its Opposition to the Motion for Preliminary Injunction:

Declaration of Gail B. Mahady	
Objectionable Evidence	Basis for Objection
The clinical data clearly show that the product provides five hours of energy, as Living Essential advertises. ¶ 3. In my opinion, Living Essentials advertising claims are supported by the Blum clinical trial and by previously published medical and scientific literature. ¶ 8.	These statements are conclusory and Mahady does not establish any evidentiary foundation for the conclusions. [The clinical trial concludes that less than 60% of subjects experienced 5 hours of energy after drinking *5-hour Energy*® and that approximately 24% of subjects experienced a moderate to severe "crash."]
In addition, it appears that Dr. Davis does not have a copy of this clinical trial, thus his comments about the study were made with [sic] having thoroughly reviewed the trial. ¶ 3. The statements by Hansen on page 4 of the memorandum appear to be based on incomplete information obtained from websites, as they do not have a copy of the report describing the clinical trial and thus could not have possibly read it. ¶ 13. Thus, it is impossible to claim that 5-hour	Lack of personal knowledge (F.R.E. 602); Mahady does not establish any evidentiary foundation for this conclusion. [Hansen had a copy of the study before Living Essentials filed it with the Court]

ENERGY® produce provides no energy as also claimed by Dr. Davis, as he apparently has not reviewed the data. ¶ 13.	
The Blum clinical trial of 5-hour ENERGY® was performed by Dr. James Blum, who is an Epidemiologist and Biostatistician, at the University of New England Medical School. ¶ 8.	Lack of personal knowledge (F.R.E. 602); Mahady does not establish any evidentiary foundation for this assertion. [James Blum was not affiliated with the University of New England in 2007. The University of New England does not have a medical school.]
The clinical site was located at the Southern Maine Research Center (independent medical research center) located at 344 Cumberland Street, Westbrook, Maine. ¶ 8.	Lack of personal knowledge (F.R.E. 602); Mahady does not establish any evidentiary foundation for this assertion. [The building located at 344 Cumberland Street, Westbrook Maine is a residence. There is no research facility at that address]
Approval to perform this study was obtained from the Institutional Review Board of the University of New England Medical School. ¶ 8.	Lack of personal knowledge (F.R.E. 602); Mahady does not establish any evidentiary foundation for this assertion. [The Institutional Review Board of the University of New England never gave approval for this study]
The 5-hour ENERGY® product contains a dose of caffeine comparable to that of a cup of the leading premier coffee per serving, thus falls within the acceptable range for a energy effect. ¶ 18.	Mahady's statements are conclusory and she does not establish any evidentiary foundation for these conclusions. [According to her own research a person must ingest at least 150 mg. of caffeine to

	experience performance "enhancement." *5-hour Energy*® caffeine content is approximately 85 mg.]

DATED: September 8, 2008

Respectfully submitted,

SOLOMON WARD SEIDENWURM & SMITH, LLP

By: /s/ Edward J. McIntyre
NORMAN L. SMITH
EDWARD J. MCINTYRE
WILLIAM N. KAMMER
Attorneys for Hansen Beverage Company

CERTIFICATE OF SERVICE

I caused the **HANSEN BEVERAGE COMPANY'S OBJECTIONS TO THE DECLARATION OF GAIL MAHADY FILED IN SUPPORT OF LIVING ESSENTIALS' OPPOSITION TO THE MOTION FOR PRELIMINARY INJUNCTION** to be served in the following manner:

Electronic Mail Notice List

The following are those who are currently on the list to receive e-mail notices for this case.

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Manual Notice List

The following is the list of attorneys who are not on the list to receive e–mail notices for this case (who therefore require manual noticing).

None.

/s/ Edward J. McIntyre
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UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

HANSEN BEVERAGE COMPANY, a Delaware corporation, Plaintiff, v. INNOVATION VENTURES, LLC dba LIVING ESSENTIALS, a Michigan corporation, Defendant.	CASE NO. 08-CV-1166 IEG (POR) **FURTHER DECLARATION OF RODNEY SACKS IN SUPPORT OF HANSEN BEVERAGE COMPANY'S MOTION FOR PRELIMINARY INJUNCTION** Date: September 15, 2008 Time: 10:30 a.m. Courtroom: 1 Hon. Irma E. Gonzalez

Rodney Sacks declares:

1. I am the Chairman of the Board and Chief Executive Officer of Hansen Beverage Company ("Hansen"). The facts in this declaration are based on my own personal knowledge.

2. Living Essentials has at least three *5-hour Energy®* products on the market; its regular *5-hour Energy®* ("Regular"); *5-hour Energy®* Extra Strength ("Extra Strength"); and *5-hour Energy®* decaf ("Decaf"). Based on these products' labels, the ingredients contained in each of the three products vary. For example, Extra Strength has more Niacin than Regular, but Decaf has none. Each has different amounts of "energy blend" – Regular has 1870 mg, Extra Strength has 1950 mg and Decaf has 2106 mg. The "energy blend" for Decaf is also different than Regular and Extra Strength because it contains Choline, while Regular and Extra Strength contain Citicoline. Decaf has about as much caffeine as half a cup of decaffeinated coffee, while Regular and Extra Strength contain about as much caffeine as a cup of the leading premium coffee. Decaf also contains an "Enzyme Blend" not found in Regular or Extra Strength.

3. The differences in the type and amount of ingredients between these three products is important because the Blum clinical trial does not indicate which *5-hour Energy®* product was given to the subjects for testing purposes. Since only one result is indicated for *5-hour Energy®* in Blum's clinical study, this strongly suggests that only one of these three products was used in the trial. Therefore Living Essentials has no data regarding its other two products, yet all three bear the *5-hour Energy®* name, in support of the claim that each actually provides energy lasting 5 hours.

4. Similarly, Hansen's Monster Energy® brand has a variety of products other than its "regular" Monster Energy® drink, including Lo-Carb Monster, Monster Khaos, Monster Assault, Monster M-80, Monster Heavy Metal, and Monster Mixxd. Each product's ingredients varies to a limited extent from the others. Again the Blum clinical trial does not mention which Hansen's Monster Energy® drink product was tested. Absent such information, it is impossible to determine which products Blum actually used for purposes of

comparison in his study.

5. I have reviewed the comparative advertisement on Living Essentials' product website (www.5hourenergy.com/compare.asp). The image of the "Popular Canned Energy Drink" on that web site is clearly a reference to Hansen's Monster Energy® drink – the black can with the florescent lime green writing on the can is the same distinct combination used by Hansen for its Monster® Energy drink.

6. The ingredients of the side-by-side comparison with the "Popular Canned Energy Drink" reinforces the fact that the comparison is to Monster® Energy drink. The amount of calories, sugar, carbohydrates, sodium, niacin, Vitamin B6, and Vitamin B12 in Monster Energy® match exactly those ingredients enumerated on the comparative advertisement. Living Essentials actually misrepresents the amount of "energy blend" found in an 8 oz. can of Monster Energy®, by falsely advertising that it has exactly half the energy blend (1250 mg.) than it actually does (2500 mg.).

7. Hansen's Diet Red Energy, to which Living Essentials refers, contains glucose. It is the glucose in combination with the other ingredients, including caffeine, found in that product that gives the user an energy "boost." Hansen makes no claims about the duration of the energy "boost" in this product that has no relevance to Living Essentials "clinical trial" or its claims.

I declare on penalty of perjury under the laws of the State of California and the United States of America that the facts in this declaration are true and correct, based on my own personal knowledge and on information from our science expert which I believe to be true and correct, and that I executed this declaration in Corona, California, on September 8, 2008.

RODNEY SACKS

CERTIFICATE OF SERVICE

I caused the **HANSEN BEVERAGE COMPANY'S REPLY TO LIVING ESSENTIALS' OPPOSITION TO ITS MOTION FOR PRELIMINARY INJUNCTION** to be served in the following manner:

Electronic Mail Notice List

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Manual Notice List

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None.

/s/ Edward J. McIntyre
EDWARD J. MCINTYRE

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Attorneys for HANSEN BEVERAGE COMPANY

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

HANSEN BEVERAGE COMPANY, a Delaware corporation, Plaintiff, v. INNOVATION VENTURES, LLC dba LIVING ESSENTIALS, a Michigan corporation, Defendant.	CASE NO. 08-CV-1166 IEG (POR) **FURTHER DECLARATION OF THOMAS P. DAVIS, Ph.D. IN SUPPORT OF HANSEN BEVERAGE COMPANY'S MOTION FOR PRELIMINARY INJUNCTION** Date: September 15, 2008 Time: 10:30 a.m. Courtroom: 1 Hon. Irma E. Gonzalez

Thomas P. Davis, Ph.D. declares:

1. I have read and analyzed the 27-page "Final Report" that is linked to the web page found on the Internet at http://dsresearchgroup.com. It is titled "A Randomized, 3-Arm Comparative-Controlled, Double-Blinded, Cross-Over-Group, Clinical Trial to Test the Short-Term Efficacy and Safety of Company ABC's Energy Drink™ In a Comparison with Other Energy Drinks". I have these comments and observations about that Report.

2. On its first page, the author noted that "subjects will be instructed that these blends are intended to induce energy increases without the need to make major behavioral changes." This was a fundamental flaw of this study because it immediately introduced a bias into it. Armed with this prior information, the participants are immediately "anticipating" that they "will feel more energy." All of the endpoints of the study were based upon self-reporting, and therefore this was a significant failure in study design, rendering all of the results biased and hence worthless.

3. Page 2 of the Internet Report stated that all subjects would be "randomized for the metabolic testing." Further remarks concerning metabolic testing and procedures appear in three places on the following page. Metabolic testing would have been an important and crucial component in the design of a valid clinical trial because proper metabolic testing would have shown the direct, measurable effect (if any) of the drinks and products tested on increases in human metabolic activity (i.e., oxygen consumption) versus the placebo. The researchers knew this as it was considered an essential element of the "Study" before it was ever started, but the data is not presented in any form in the "Final Report" which clearly invalidates the "Study" for this reason alone. Energy from humans is always measurable as liters of oxygen consumed per minute in any physician's office where the metabolic/exercise machine is set up. Tellingly I find no results of that testing in the Internet Report and believe that it was not done or, if it was done, the data did not support the 5-Hour product advertisements. Again because the endpoints were based upon subjective reports, the absence of measurable, quantitative, metabolic testing results eliminated any scientific validation of the "Study's" reported results, making it worthless.

4. The results of a clinical trial of this sort can only be validated by statistical testing according to generally accepted statistical criteria. The Internet Report discussed the use of regression analysis at page 6 and the Chi-Square test and Fisher's Exact Two-Tail t-test on page 7. These are statistical methods of analysis commonly used to attempt to validate results in such studies where the "sample numbers or cells" are small. The Report properly noted on page 7 that the Fisher's t-test is particularly necessary with small cell sizes. This Report is based upon the responses of a very small sample size and that is why Fisher's t-test was so important. However, I could find little to NO reference to the results of these important statistical tests nor the level of statistical significance from the testing of the data sets in this "Final Report."

5. Regression analysis would have been necessary for this study but again no results of the statistical testing was provided. One can assume either that the results from the statistical testing did not agree with what the principal investigator or the study designer wanted the data to report or that the testing was simply not done. In any event, the "Study" is inherently defective and the results incredible.

6. There are no reported results from the use of any of these statistical methods on the data sets anywhere in the Internet Report, suggesting to me that they were never performed or the results from the statistical tests were not favorable to the 5-Hour product. If they were performed, then the failure to report their results is strongly indicative of the fact that the numerical results were not statistically significant. In fact, that lack of statistical significance is suggested in the statement at the very end of page 27 that "the actual peak levels achieved by each drink were comparable and **no statistical differences were found.**" If no statistical differences were found, what test was used to support that statement? If NO differences were noted, at WHAT LEVEL of statistical significance was this found?

7. Another flaw in this "clinical trial" was its failure to isolate the effects of the levels of caffeine consumption by the participants as part of their regular diet. Caffeine is well known to affect blood pressure, heart rate, and several perceived "feelings" of energy. The Table on page 11of the Report identifies 19% of the subjects as not using caffeine of any

sort but 55% as using the equivalent of at least two cups (the volume of coffee consumed is unknown) a day with some 20% using five or more cups. Nevertheless this variable was never isolated in the study to control the effects of the caffeine regularly present in the different subjects' bodies since diet was not to be controlled in this "Study." It is known that the caffeine content of regular coffee can range from 150 to 350 milligrams of caffeine per 12 ounces, so the different study participants consumed from zero up to 1750 milligrams of caffeine per day from coffee alone while participating in the study. This uncontrolled variable could have caused any "self-perceived response" to any question asked in this "Study." Because one compound that can cause a "perception" of "energy" is caffeine and the products tested only contained between 85 and 175 milligrams of caffeine, the uncontrolled and variable consumption of caffeine by the study participants clearly affected all results in an uncontrolled manner and the "Study" is a failure and worthless.

8. Finally the first page of the Report stated that each test day, the subject would receive a "placebo or one of the three products." However the Report does not contain any listing or tabulation of the self-reports of any subject who received the placebo, a very strange omission. Any expert in ANY clinical study knows the power of the "placebo effect." It is also well known by all lay people who read any literature or watch any internet news service that the placebo effect is real. NO placebo data is ever shown yet the placebo was "tested" per the Report. In this case one must question if any/all the results were "masked" by a strong placebo effect and NO result in this "Final Report" is valid. One can not "pick and choose" results to show in a "Final Report" because this is not valid.

I declare under penalty of perjury under the laws of United States of America that the facts in this declaration are true and correct, based on my own personal knowledge and on generally accepted science which I believe to be true and correct, and that I executed this declaration on September 8, 2008.

Thomas P. Davis, Ph.D.

THOMAS P. DAVIS, Ph.D.

9-8-08

CERTIFICATE OF SERVICE

I caused the **FURTHER DECLARATION OF THOMAS P. DAVIS, Ph.D. IN SUPPORT OF HANSEN BEVERAGE COMPANY'S MOTION FOR PRELIMINARY INJUNCTION** to be served in the following manner:

Electronic Mail Notice List

The following are those who are currently on the list to receive e-mail notices for this case.

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Manual Notice List

The following is the list of attorneys who are not on the list to receive e–mail notices for this case (who therefore require manual noticing).

None.

/s/ Edward J. McIntyre
EDWARD J. MCINTYRE

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Attorneys for HANSEN BEVERAGE COMPANY

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

HANSEN BEVERAGE COMPANY, a Delaware corporation, Plaintiff, v. INNOVATION VENTURES, LLC dba LIVING ESSENTIALS, a Michigan corporation, Defendant.	CASE NO. 08-CV-1166 IEG (POR) **DECLARATION OF RON MORRISON, Ph.D., IN SUPPORT OF HANSEN'S MOTION FOR PRELIMINARY INJUNCTION** Date: September 15, 2008 Time: 10:30 a.m. Courtroom: 1, Fourth Floor Judge: Hon. Irma E. Gonzalez

Ron Morrison declares:

1. I am a Professor in the Department of Philosophy and Religious Studies at the University of New England. I have a bachelor's degree from the University of Maine, and my M.A. and Ph.D. are from Emory University. My research interests include bioethics and environmental philosophy.

2. I am Chair of the University of New England's Institution Review Board ("IRB"). Our IRB meets approximately once per month throughout the year to review research protocols involving human subjects that have been submitted by faculty, students, staff, or administrators of the University.

3. I have particularly reviewed paragraph 8 of the declaration of Gail B. Mahady, Ph.D., and certain statements in it concerning a Dr. James Blum.

4. I am personally aware of the members of the faculty of the University of New England. Dr. Blum is not an epidemiologist and biostatistician at the University of New England Medical School as asserted in paragraph 8. In fact, our University has no "Medical School." Our University does have a College of Osteopathic Medicine, but Dr. Blum has not been associated with that school as an adjunct faculty member since 2005_.

5. Paragraph 8 of Dr. Mahady's declaration states that Dr. Blum obtained approval to perform a clinical trial of 5-hour ENERGY® from our University's IRB. That is not a true statement. The protocol for that study was never approved by the University of New England IRB.

I declare under penalty of perjury under the laws of the United States of America that the facts in this declaration are true and correct and that I executed this declaration on September 8, 2008.

[signature]

Ron Morrison, Ph.D.

CERTIFICATE OF SERVICE

I caused the **DECLARATION OF RON MORRISON, Ph.D., IN SUPPORT OF HANSEN'S MOTION FOR PRELIMINARY INJUNCTION** to be served in the following manner:

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Manual Notice List

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None.

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Attorneys for HANSEN BEVERAGE COMPANY

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

HANSEN BEVERAGE COMPANY, a Delaware corporation,

Plaintiff,

v.

INNOVATION VENTURES, LLC dba LIVING ESSENTIALS, a Michigan corporation,

Defendant.

CASE NO. 08-CV-1166 IEG (POR)

FURTHER DECLARATION OF WILLIAM N. KAMMER IN SUPPORT OF HANSEN BEVERAGE COMPANY'S MOTION FOR PRELIMINARY INJUNCTION

Date: September 15, 2008
Time: 2:00 p.m.

Hon. Irma E. Gonzalez

I, William N. Kammer, declare:

1. I am a partner in the firm of Solomon Ward Seidenwurm & Smith, LLP, and one of the attorneys representing Hansen Beverage Company in this matter.

2. I personally initiated a number of Internet searches during the month of August to obtain additional information about 5-Hour Energy and the "clinical trial" referred to on various pages of its website. I was initially unsuccessful in my efforts to locate any documents or references related to that "clinical trial."

3. I renewed my efforts during the week of August 25th because I anticipated the Defendant's use of the "clinical trial" in 5-Hour's Opposition to Hansen's Motion For Preliminary Injunction. This time I was successful. By using a variety of search terms other than "5-Hour Energy" and certain misspellings, Google located for me an Adobe .pdf file linked to the home page of an entity I had not heard of, the "Dietary Supplement Research Group." Its home page is located at http://dsresearchgroup.com. Its web pages include a list of consultants, and James M. Blum, Ph.D., is described as "Research Director, Epidemiologist, Engineer." Its web pages also include a client list, but the list does not include the Defendant in this case.

4. On the right-hand side of its home page is a link labeled "Clinical Trial-ABC Energy Drink." Clicking on that link downloads the Adobe file that Google had returned in its search results. That Adobe .pdf file was a 27-page document, a "Final Report" of "A Randomized, 3-Arm Comparative-Controlled, Double-Blinded, Cross-Over-Group, Clinical Trial to Test the Short-Term Efficacy and Safety of Company ABC's Energy Drink™ In a Comparison with Other Energy Drinks". It was dated May 11, 2007. Exhibit 1 to this Declaration is a copy of the Report.

5. On almost all of its 27 pages, the charts and statistics were labeled with non-descript names such as "Company ABC" and "Product 1". However, page 24 was not completely redacted, and one bar graph contained the labels "Living Essential", "Five-Hour", "Red Bull", and "Monster." I assume Google had retrieved, indexed, and stored that report and returned the .pdf file among the search results because of the labels on page 24.

6. I reviewed the findings, statistics, and graphs of the report of "Company ABC's Energy Drink", compared them to the information on the web pages of 5-Hour, and concluded that Company ABC was Innovation Ventures, LLC, dba Living Essentials. References and data throughout the report to "Product 1" were to a 5-Hour Energy product. "Product 2" was a Red Bull beverage, and "Product 3", a Hansen Monster drink.

7. I immediately reported my conclusions to the lawyers in our firm, to our client, and to Thomas P. Davis, Ph.D., whose declaration we had filed in support of the present motion. I also sent all of them a copy of the report I had downloaded from the Internet. All of this occurred during the week of August 25th and before Innovation Ventures, LLC, filed its response to Hansen's motion at 4:47 p.m. and its motion to file Exhibit C to the Declaration of Scott Henderson Under Seal at 5:01 p.m. on Friday, August 29, 2008.

8. Earlier that afternoon, Nathan Handler, one of the attorneys for the Defendant, had emailed three attorneys in our office and offered to provide a copy of the proposed Exhibit C but for "outside attorneys' eyes only". Because it was the Friday afternoon before the Labor Day weekend, two of those attorneys were absent from our office. Norman Smith referred the email to me, and I replied at 3:45 p.m. that I would be willing to receive the document but only with an agreement to treat the report as "'confidential – outside attorney and expert witness eyes only' (including Dr. Davis)". About twenty minutes later, Mr. Handler rejected my proposal. At 5:12 p.m., I emailed him and agreed to accept a copy of Exhibit C on the basis of "outside attorneys only" until the Court's disposition of the motion to seal. Mr. Handler sent me a copy of Exhibit C to the Henderson Declaration at 5:17 p.m. Hansen reserves the right to show that Exhibit C to its experts and seek their further comment.

I declare under penalty of perjury under the laws of the United States of America that the preceding is true and correct and that I executed this Declaration on September 8, 2008.

William N. Kammer

William N. Kammer

CERTIFICATE OF SERVICE

I caused the **FURTHER DECLARATION OF WILLIAM N. KAMMER IN SUPPORT OF HANSEN BEVERAGE COMPANY'S MOTION FOR PRELIMINARY INJUNCTION** to be served in the following manner:

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Manual Notice List

The following is the list of attorneys who are not on the list to receive e–mail notices for this case (who therefore require manual noticing).

None.

/s/ Edward J. McIntyre
EDWARD J. MCINTYRE

Dietary Supplement Research Group

FINAL REPORT

**A Randomized, 3-Arm Comparative-Controlled, Double-Blinded, Cross-Over-Group, Clinical Trial to Test the Short-Term Efficacy and Safety of Company ABC's Energy Drink™
In a Comparison with Other Energy Drinks**

May 11, 2007

PROTOCOL CONCEPTS

- Prospective, randomized, double blind, comparative-product clinical trial
- This trial had IRB approval;
- Randomization determined on any given test day, which product an individual would take (placebo or one of the three products);
- There was a minimum of a 48-hour washout period. It was important to allow each subject time to completely recover from their test day;
- All subject contact was with a study coordinator or research nurse who was blinded to the randomization scheme
- This was a single-center, prospective, randomized, double-blinded, and product-controlled, crossover-group-design clinical trial of Company ABC's Energy Drink™ versus two other energy blends in subjects who are wishing to assess these products for increased short-term energy.
- Subjects were recruited from the greater Portland, Maine area, through CATV advertising.
- At the outset, subjects will be instructed that these blends are intended to induce energy increases without the need to make major behavioral changes. If they wish to participate, subjects must do their best to keep their diet patterns as consistent as possible throughout the study period (approximately four weeks). With respect to food, we will strongly urge subjects to be consistent with the TYPE and AMOUNTS of food consumed during the study period. We want subjects to keep their normal patterns of diet and wish to avoid subjects changing their fundamental diets during the four weeks of the study. We will explain that the product has the possibility of altering their appetite levels during the testing day. We plan to use food logs and to train our nurses to gauge the quantity of food intake and type of food consumed.

Initial Visit

- Consenting Process:
    - Following a successful screening phone call, in which the research staff briefly explained the study and subject responsibilities, queried the potential subject about availability, some medical conditions that might exclude them, and answered any questions.

- An appointment was set for an initial meeting;
- At their Initial Visit, potential subjects were given a copy of the informed consent (IC) to review. Subsequently, research staff (PI or study coordinators) thoroughly reviewed the consent form with each prospective subject according to appropriate guidelines. Each paragraph in the IC was reviewed and subjects were allowed adequate time to make an informed decision. Subjects were allowed to take the IC home to review with family members or their medical provider.
- If agreed, both reader and subject will sign according to guidelines; subjects signed the back sheet and initialed each page;
- No procedures were done unless signed consent has been obtained.

- After consenting, subjects had their weight, height, blood pressure, pulse, and blood glucose measured.
- If a subject medically qualified for the study with respect to glucose control (non-fasting blood glucose less than 140 mg/dL, fasting less than 126), subjects were allowed to continue in the study;
- For those that failed their glucose numbers, permission from our study physician or their own physician were obtained; NOTE: we did not have any subjects in this study that failed their initial glucose levels;
- All subjects at this point will be randomized for the metabolic testing. Those randomized to receive the metabolic testing will have this testing conducted during the run-in test days. Actual product randomization will not occur until the first test-day.
- All subjects will have blood drawn for a comprehensive metabolic profile for the purposes of screening. These results were reviewed prior to their day 1 testing. Some abnormal labs would have resulted in disqualification, such as extremely elevated serum creatinine, BUN, liver enzymes, and related levels. Thankfully, no disqualifications occurred in this population, although some subjects had slightly elevated laboratory values. Each set was reviewed and elevated values were reviewed with our medical director. There was no follow-up lab work scheduled in this study because these energy drinks provide no reason to alter chemistries.
- Females of child-bearing potential provided a urine sample for pregnancy testing. Positive pregnancy testing would have been cause for disqualification although none were and all females were allowed to continue.

Test-Day Routines

- There were two test days during the baseline run-in period for the purpose of establishing normal existing patterns of diet and exercise. Both test days will include the exercise component while the second test day will also include cognitive testing.
- These days had identical routines as the experimental test-days.
- Following the two baseline testing days, subjects were randomized. Randomization was equal: Each subject will have an equal chance of receiving either one of the three drinks at any one testing days. See the figure on Page 12 for an accurate simulation of this approach.
- At the Initial Test-Day Visit, subjects will receive either ABC's Energy™ or one of the two look-alike control drinks for a full day testing period.

- Subjects will complete self-reporting questionnaires at the Initial Visit, run-in test-days, and each of the six testing days.
- On each testing day, subjects will be asked to have breakfast upon waking.
  - They will visit the research clinic as soon after their breakfast as possible, where they will be measured and take their initial dose.
  - Those randomized for metabolic testing will have their initial metabolic test during the morning session.
  - Subjects will be reminded on the use of their pedometers.
  - They will then leave the Clinic and continue on their day until their noon Clinic appointment.
  - Around the noon hour, depending on whether it is an "A" or a "B" day, they will either (a) exercise according to their individualized plan (walking, jogging, tennis, equipment, etc.), and return to the Clinic afterwards for assessment, or (b) report to the Clinic for their VIGIL cognitive test.
  - Subjects must report to the Clinic in the late afternoon to report their experiences.
  - Subjects will be allowed to take an additional dose in the afternoon if they fell they need to in order to properly function. That is, if their afternoon energy level falls near or below their morning baseline period and they need the energy to work or perform in a normal manner.
- Subjects will report to the Clinic at approximately the same time for each visit. Since we need the subjects at the Clinic in the morning for the metabolic testing, all visits must be in the morning.
- Subjects must be available on the morning following each test day for a series of follow-up questions;
- The single site is an independent research facility where qualified research staff will see all subjects at each clinic visit (SOP; 2.2 The Research Staff).

Blinding Aspects and Procedures

- This trial is double-blinded;
- The identity of the specific treatment arm is not available to the clinical team, unless a medical emergency arises. The consulting physician is always able to gain access to this information.
- We use a multi-step process that assures this confidentiality. One of two study coordinators prepares the product bags that are given to each subject. Each bag is marked with a number that includes the study number and specific subject number. For example 12123 would be decoded as study number 121 and subject number 23.
- The study coordinators keep secured records as required by the IRB that includes the randomization scheme, subject identifiers, and other pertinent information. This information is kept from the nurses and biostatistician. In cases of medical problems the consulting physician or nurse typically acts without knowledge of the randomization. However, if the medical condition is considered serious the code may be broken. The IRB and the study sponsor will be notified under these circumstances as required by IRB guidelines.

Product Usage:

Taken once a day, in the morning;
Product delivered in cups;
Products were masked with small amounts of a placebo mix;

Placebo Mix:

Diet orange or diet Dr Pepper with tiny amounts of raw dried herbs

Inclusion Criteria

- Women and men who are interested in assessing commercially available energy drinks, have BMI's in the range of 20 to 37.5 m/kg^2, and are willing to exercise on the testing days;
- Women and men who are 18 to 60 years of age, inclusive, at the Initial Visit;
- Subjects in physical condition able to handle an increased energy period comfortably;
- Subjects who pass a compliance-screening test
- Subjects able to tolerate the active product and placebo
- Subjects who sign a consent form

Exclusion Criteria

Subjects who met any of the following exclusion criteria were not eligible for participation in this clinical trial:

- Were unwilling or unable to comply with any aspect of the clinical trial protocol;
- Were using any prescription or non-prescription products for energy or weight loss in the past 4 weeks; this list includes all fiber or laxative products;
- Are allergic to or express problems with any of the energy drink ingredients;
- Who had lost/gained more than 10 pounds of body weight in the last 3 months;
- Had severe co-morbid disease including cardiac, pulmonary, renal, hepatic, or active cancer; had any disease or condition that in the investigator's opinion compromises the integrity of the clinical trial or the safety of the subject;
- Consume alcohol at an elevated level; as defined as consumption of more than 14 standard alcoholic drinks per week; 12 ounces of beer = 4 ounces of wine = 1 ounce of hard liquor.
- Were insulin dependent diabetic;
- Had uncontrolled hypertension (defined as systolic blood pressure greater than 160 torr or diastolic blood pressure greater than 110 torr or by the study physician). Subjects taking antihypertensive medications were reviewed by the study physician prior to enrollment (randomization).
- Had had a surgery or a hospitalization within the past 3 months;
- Had an acute illness;
- Had a Body Mass Index (BMI) of less than 20 or greater than 40.0 m/kg^2;
- Had participated in a clinical trial in the past 4 weeks;
- Were taking methadone, insulin, anticoagulants, or similar medications;

- Women who were nursing, pregnant, or actively trying to become pregnant;

Severe co-morbid disease is defined as any condition that would cause severe limitations or inability to carry out usual activities of daily living.

The exclusion criteria identified above are based upon general safety concerns identified with the condition and/or product from recommendations made by the study physician, confounders identified by the biostatistician, or information identified in product ingredients' research.

Caution Criteria

Subjects who meet any of the following caution criteria will be strongly advised to consult with their primary care physician (PCP) prior to participating in this clinical trial:

- Those with a propensity to allergic reaction.
- Had a blood glucose (non-fasting, measured at the Initial Visit) of greater than 140 mg/dL;
- Had a fasting blood glucose of greater than 126 mg/dL evident with laboratory testing;

PRIMARY END-POINTS:

The primary efficacy endpoints are (1) research staff measurements and self-reports of:

- Energy, levels and strength
- Duration of elevated energy levels,
- Temporal sequence of energy levels throughout the day
- Timing of the 'crash'
- Level of the 'crash' compared to baseline
- Next day energy, fatigue, and alertness
- Exercise level
- Metabolic rates (subset)

The assessment of research staff measurements will be compared within subjects from measurements made during the run-in (at baseline) compared to the six test days.

Assess 'healthy energy' levels for the following time frames:

- Five, seven and nine-hour mark
- Total time of extended energy
- Peak energy levels
- Next morning energy levels

Assess the anticipated 'crash' following a period of extended energy:

- 'Crash' will be defined compared to each subjects' baseline level of energy and cognitive functioning, diagram a temporal relationship from beginning to the end of the day

Primary Endpoint: Energy

The difference between the end-of-the study weight and the baseline weight will be calculated for each subject. These differences will be tested statistically using unpaired t-tests (equal or unequal variances based on the actual variances) using the SPSS software (version 12, Chicago, IL.).

Differences of the means and the categories will be stratified by age, gender, baseline BMI, baseline weight, and the highest tertile of a co-morbid condition status. These potential confounders are historically the most important and thus require adjusting.

Regression models will be fitted using weight as a continuous variable and as a categorical outcome marker to determine if there are any additional confounders to report. These models will be helpful in explaining the results if any of the baseline characteristics are either clinically or statistically different.

Other End-Points:

- Taste
- Recommend product
- Quality-of-Life

ANALYTICAL METHODS:

Methods:

- Answers from survey tools were coded from 1 to 10
- Answers from the follow-up questionnaires were subtracted from each subjects' baseline data to create the outcome measures

Example:

Please write in the appropriate space, on the scale below, your rating for the symptoms:

0 1 2 3 4 5 6 7 8 9 10

For example, a subject answering the question about x at baseline and final give the following answers corresponding to the subsequent codes,

Time	***Answer***
Baseline	*8*
Final at 3-months	*2*

The subtraction of the codes renders a point improvement for this subject on this question:

8 – 2 = 6 point improvement

- The answers for the two groups (placebo and treatment) for each symptom were summed. This forms the basis of the results.
- Differences in the means between the treatment and placebo groups were analyzed using the paired or unpaired t-test, where statistical significance was pre-determined to be < 0.05.

Categorical Analysis:

- One-to-two point differences have been classified as "some improvement", while three-to-four point differences as "significant", and five or more point improvements as "dramatic".

    - No Improvement
    - Any Improvement: One point or greater
    - Some Improvement: Specifically one-to-two point improvement
    - Significant Improvement: Specifically three-to-four point improvement
    - Dramatic Improvement: Specifically five-or-more point improvement

- All categories were analyzed using the Chi-Square test. Some analyses used Fisher's Exact Two-Tail t-test, due to the small cell limitations. Fisher's is another type of chi-square test that must be utilized during scenarios of small cell sizes.
- These category improvements were determined a priori by the medical advisory group

TRIAL RESULTS

A total of 63 subjects consented, but only 58 began the trial. Forty-two individuals completed all the testing aspects. The drops were self-imposed.

Baseline Characteristics

The following data defines the study population.

Parameter	Percentages
Males	63%
Females	37
Black	11.1%
Hispanic	7.4
White	81.5

Clerical	4%
Craftsperson / technical	11
Management	4
Professional	11
Service Industry	22
Student	15
Not Working	22
Number of Hours Working	**Percent**
Full-Time	42%
Part-Time	26
N/A for Hours working	22

Vital Statistics

Parameter	Mean	Std. Dev.
Age	27.4	11.1
Height	68.4	4.5
Weight	165.2	41.4
BMI	26.8	5.5

Age Distribution

Age Categories	Percentage	Cumulative Percent
18 – 19	16.3%	16.3
20 – 24	32.7	49.0
25 – 29	16.3	65.3
30 – 34	6.0	71.3
35 – 39	4.0	75.3
40 – 44	6.3	81.6
45 – 49	6.0	87.6
50 – 54	10.1	97.7
55 -59	2.0	99.7

The mean age was 27.4 years with a range from 18 to 57. Even though nearly half were 24 or younger, there was a steady number of subjects from 30 onward demonstrating that this represented a wider range than just teenagers and those in their early twenties.

Alcohol Consumption

Parameter	Percentages
None	56%
<1	7

1-2	7
3-4	4
5-6	7
7-8	4
9-10	4
11-14	4

Mean Alcohol Consumption per Week

Parameter	Mean	Std. Dev.	Lower 95% Confidence Interval	Upper 95% Confidence Interval
Average Level of Alcohol per Week	1.5	2.0	0.9	2.1

The amount of alcohol consumed is remarkably low for this population. Even though this is a self-report statistic, the research staff had no reason not to believe it.

Self-Report Weekly Exercise Levels

Parameter	Percentages
<1	4%
1-2	11
3-4	15
5-6	26
7-8	15
9 or more	11

Self-Report Health Status

Parameter	Percentages
Excellent	26%
Very Good	44
Good	15
Poor	4
Fair	0

Medical History

Parameter	Percentages
Diabetes	4%

Hypertension	4
Thyroid	4
Asthma or COPD	0
Heart Disease	0
Depression	15
Serious Injury	22
Surgery	56
Kidney	0
Gallbladder	0
Liver	4
Gastrointestinal	11
Ulcer	7
Cholesterol	4
Cancer	0
Osteoarthritis	0
Rheumatoid arthritis	4
Neurological problems	0
Blood Disorders: anemia, etc.	0
Gout	0
Migraines	4
Skin Conditions	0
Diet Restrictions	1
Other	7
On Meds	30
Smoking	45
Supplements	26
Allergies	11

Despite a wide age range, this population represents a fairly healthy population with the exception of smoking and possibly depression. Smoking is high in this group but may represent the type of individual that wishes to assess energy drinks. While depression may seem high, it is not compared to the general population. Other notable low risk levels include diabetes (4%), asthma (0%), cardiac or hypertension (4%), and arthritis (4%).

Surgery Types

Type of Surgery	**Numbers**
Hip	N= 3
Tubal ligation	3
Oral surgery	3
Tonsil	2
Various	1

'Various' includes back, tonsils, hysterectomy, hernia, gallbladder, appendix, thumb, and knee

Caffeine Intake

Caffeine Per Day (cups)	Percentages
0	19%
1	23
1.5	4
2	19
3.5	4
4	12
5	12
6	4
8	4

Mean Daily Caffeine Consumption

Parameter	Mean	Std. Dev.	Lower 95% Confidence Interval	Upper 95% Confidence Interval
Average Daily Caffeine	2.0	1.9	1.4	2.5

The average amount of daily caffeine was 2 cups or equivalent with a surprisingly narrow confidence interval, despite the distribution that ranged from none up to 8.

Caffeine Types

	Percentages
Coffee	48%
Caffeinated Soda	33
Coffee and Caffeinated Soda	19
Caffeinated Teas	5

Coffee drinkers, as solo or combined, represented two-thirds of this population while soda drinkers as solo or combined represented half the group.

Energy Drinks (on average)

	Percentages
Never	61%

Occasionally	8
1 Every Other Day	8
1/Day	15
Approx 3/day	8

Mean Daily Energy Drinks

Parameter	Mean	Std. Dev.	Lower 95% Confidence Interval	Upper 95% Confidence Interval
Average Daily Caffeine	0.41	0.9	0.14	0.68

The average amount of energy drinks was less than half per day, with a corresponding 95% confidence interval between 0.14 and 0.68 drinks per day. This is remarkably LOW for a group testing these drinks and dramatically reduces potential biases in this study.

Baseline Average Energy (over the past week)

Subjects were asked to rate their average and peak levels of energy over the previous week. A rating of '0' meant the individual had almost no energy while a '5' meant they were experiencing an average amount of energy, and a '9 would be their ideal setting with everything going extremely well, just short of 'bouncing off the wall'.

We notice that this specific population exhibited a bimodal distribution, with the first peak centered on '4-5' on this scale, while a second group peaked at '7'. This indicates a normal response to this question that we have seen in other trials. It is important to remember that this is a self-report question and provides a valuable insight in how they view their average energy level and that no one can validate their responses.

Average Energy Levels Over the Past Week

10-Point Scale: 0= No Energy; 9 = Highest	**Percentages**
0	0%
1	0
2	0
3	4
4	16
5	32
6	8
7	32
8	8

9	0

Peak Energy (over the past week)

Like the questions concerning their 'average' energy, this related questions asked about their peak energy level (using the same scale).

For the most part, all subjects, except one, rated their peak above their average. The raw data shows that those reporting an average of '7 and 8' moved their peak to '9', while those reporting an average from '4' to '6' reported their peak between '6 to 8'.

10-Point Scale: 0= No Energy; 9 = Highest	Percentages
0	0%
1	0
2	0
3	0
4	4
5	0
6	4
7	32
8	20
9	40

Mean Energy Levels at Baseline

Parameter	Mean	Std. Dev.	Lower 95% Confidence Interval	Upper 95% Confidence Interval
Average Level of Energy	5.2	1.4	4.8	5.7
Peak Level of Energy	7.6	1.5	7.1	8.0

The 95% Confidence Intervals demonstrate how close the entire group was in terms of their baseline energy levels. Statistically, there were very few outside of a narrow range with respect to their baseline energy levels. This is a good finding for comparing their future experiences in assessing the various drinks.

Comprehensive Metabolic Profile Results

Laboratory Parameter	Mean	Std. Dev.
Electrolytes		
Calcium	9.63	0.26
Chloride	103.9	2.0
Potassium	4.29	0.27
Sodium	140.3	1.6
Renal Function		
BUN	12.9	3.1
Serum Creatinine (Scr)	0.93	0.15
BUN: Scr Ratio	14.2	4.2
Albumin	4.55	0.24
Proteins (total)	7.34	0.4
Globulin	2.79	0.4
Albumin Ratio	1.66	0.2
Liver Function and Related		
Bilirubin	0.61	0.3
Glucose (non-fasting)	100.9	20.8
Alkaline Phosphatase	86.9	20.1
AST	19.5	5.2
ALT	20.4	9.1

We note that no individuals in this trial had abnormal baseline comprehensive metabolic laboratory (CMP) values. All these numbers are in the normal range.

STUDY END-POINTS:

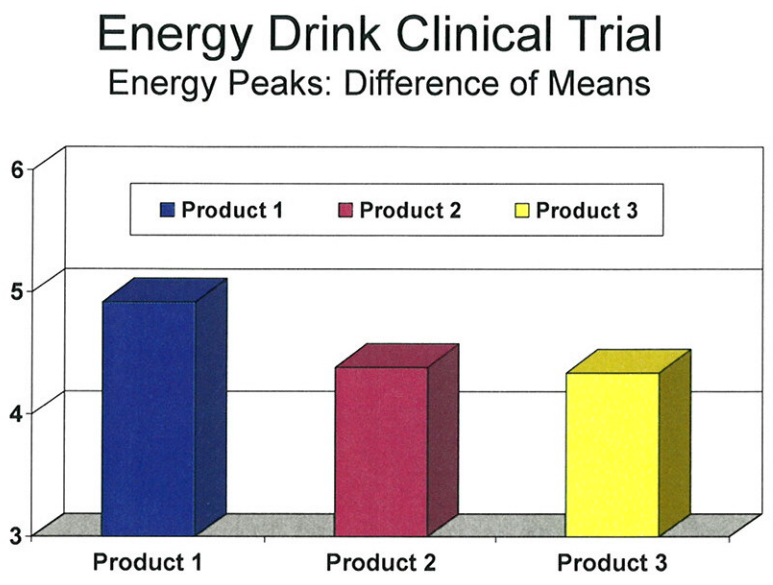
Peak Duration End-Point:

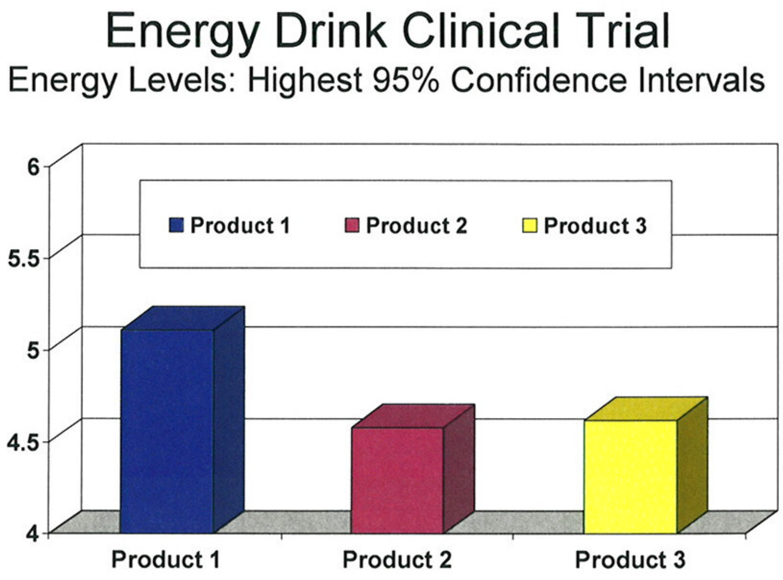
This end-point is the mean and 95% Confidence Interval (C.I.) for the number of hours that each drink showed a noted increase.

For example, Product 1 had the longest period of increased activity of 4.92 hours. Ninety-five percent of the time, one would expect that range to include the interval (C.I.) from 4.7 hours all the way up to 5.1 hours. Both Product 2 and Product 3 had similar results for their means and C.I. between these two products, but were both lower than Product 1 Energy.

Mean and Range of Energy Peaks in Hours following Ingestion

	Mean	Std. Dev.	95% Confidence Interval Lower Limit	95% C.I. Upper Limit
Product 1	4.92	0.71	4.74	5.11
Product 2	4.39	0.52	4.21	4.58
Product 3	4.34	0.68	4.11	4.59


Energy Drink Clinical Trial
Energy Peaks: Difference of Means
Product 1
Product 2
Product 3
6
5
4
3
Product 1
Product 2
Product 3

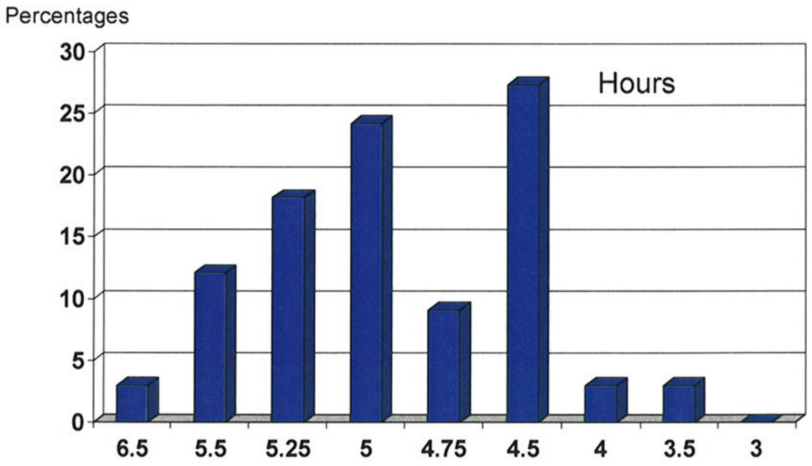

Energy Drink Clinical Trial
Energy Levels: Highest 95% Confidence Intervals
6
5.5
5
4.5
4
Product 1
Product 2
Product 3
Product 1
Product 2
Product 3

Product 1

Peak Hours	Percent	Cumulative Percent
6.5	3.0	3.0
5.5	12.1	15.1
5.25	18.2	33.3
5.0	24.2	57.5
4.75	9.1	66.6
4.5	27.3	94.0
4.0	3.0	97.0
3.75	3.0	100
3.50	0	100
3.25	0	100
3.0	0	100

Energy Drink Clinical Trial

Product 1 Energy Distribution


Percentages
30
25
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15
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Hours
6.5
5.5
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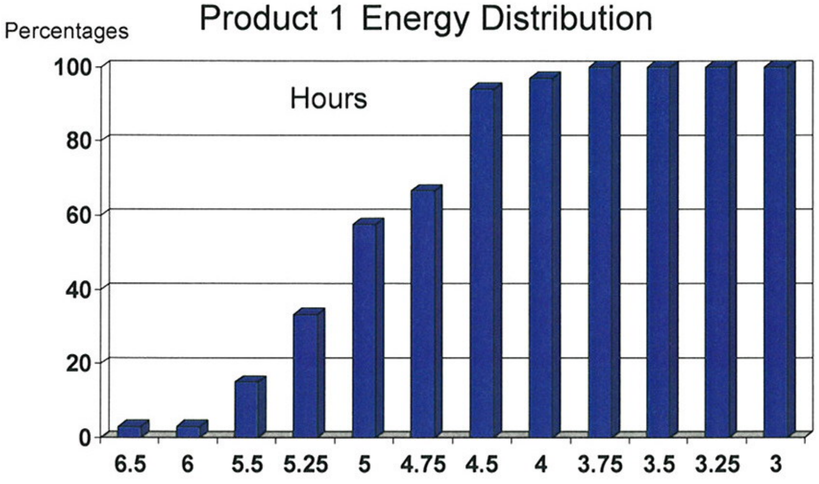
5
4.75
4.5
4
3.5
3

Energy Drink Clinical Trial Cumulative Distribution

Product 1 Energy Distribution


Percentages
100
80
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20
0
Hours
6.5
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4
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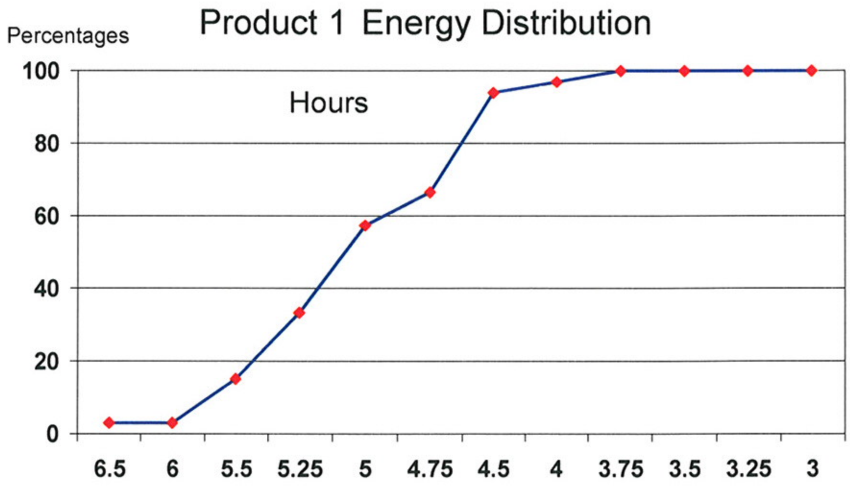
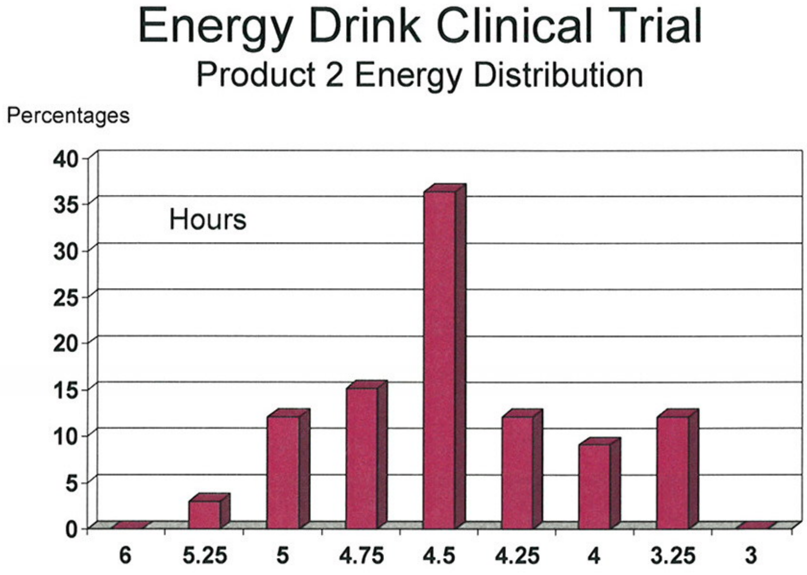
3.5
3.25
3

Energy Drink Trial
Cumulative Distribution


Product 1 Energy Distribution
Percentages
Hours
100
80
60
40
20
0
6.5
6
5.5
5.25
5
4.75
4.5
4
3.75
3.5
3.25
3

Product 2

Peak Hours	Percent	Cumulative Percent
6.0	0	0
5.25	3.0	3.0
5.0	12.1	15.1
4.75	15.2	30.3
4.5	36.4	66.7
4.25	12.1	78.8
4.0	9.1	87.9
3.25	12.1	100
3.0	0	100


Energy Drink Clinical Trial
Product 2 Energy Distribution
Percentages
40
35
30
25
20
15
10
5
0
Hours
6
5.25
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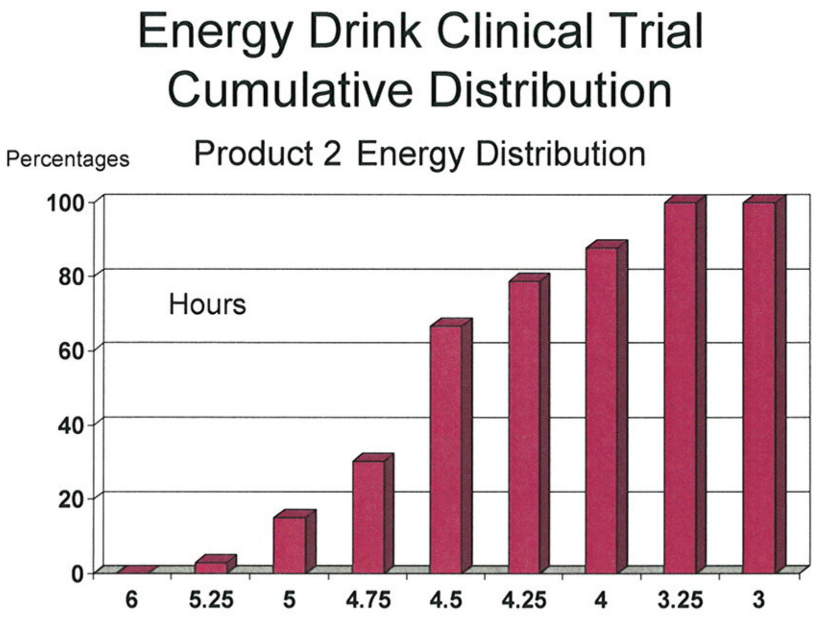
4.75
4.5
4.25
4
3.25
3


Energy Drink Clinical Trial
Cumulative Distribution
Percentages
Product 2 Energy Distribution
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80
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Hours
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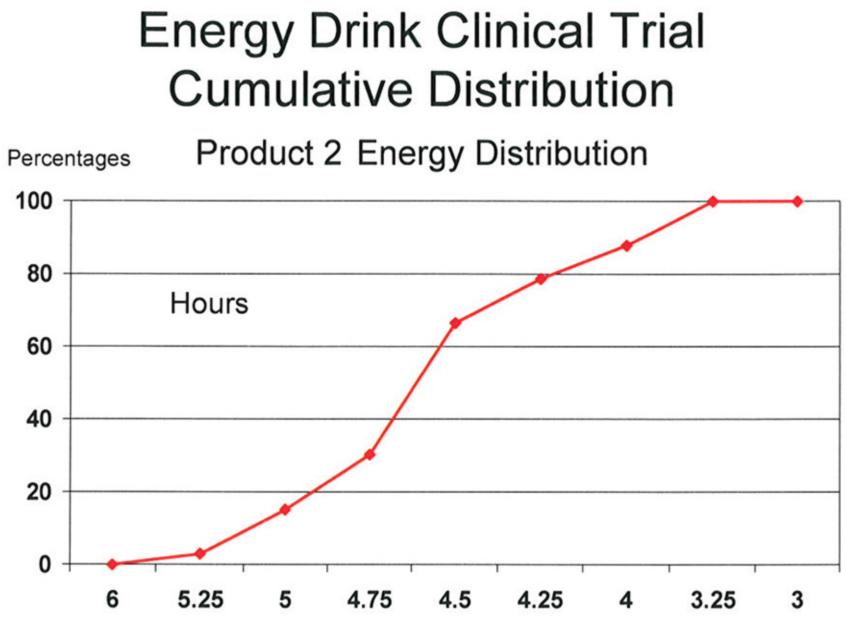
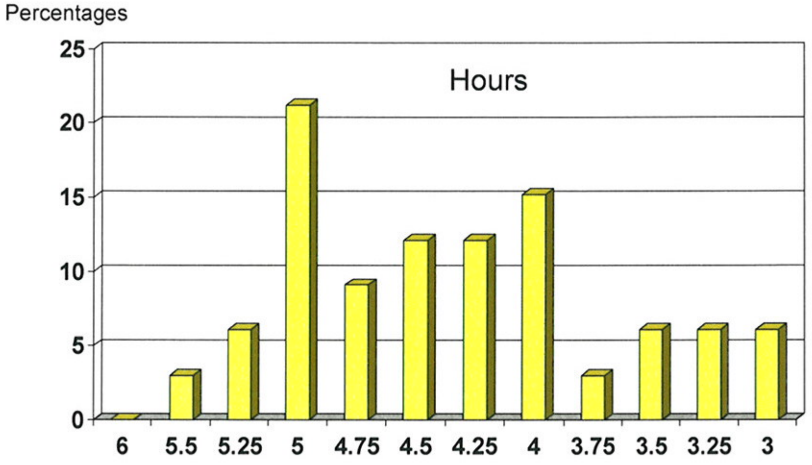
3


Energy Drink Clinical Trial
Cumulative Distribution
Percentages
Product 2 Energy Distribution
Hours
100
80
60
40
20
0
6
5.25
5
4.75
4.5
4.25
4
3.25
3

Product 3

Peak Hours	Percent	Cumulative Percent
6	0	0
5.5	3.0	3.0
5.25	6.1	9.1
5.0	21.2	30.3
4.75	9.1	39.4
4.5	12.1	51.5
4.25	12.1	63.6
4.0	15.2	78.8
3.75	3.0	81.8
3.5	6.1	87.9
3.25	6.1	94.0
3.0	6.1	100

Energy Drink Clinical Trial
Product 3 Energy Distribution


Percentages
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Hours
6
5.5
5.25
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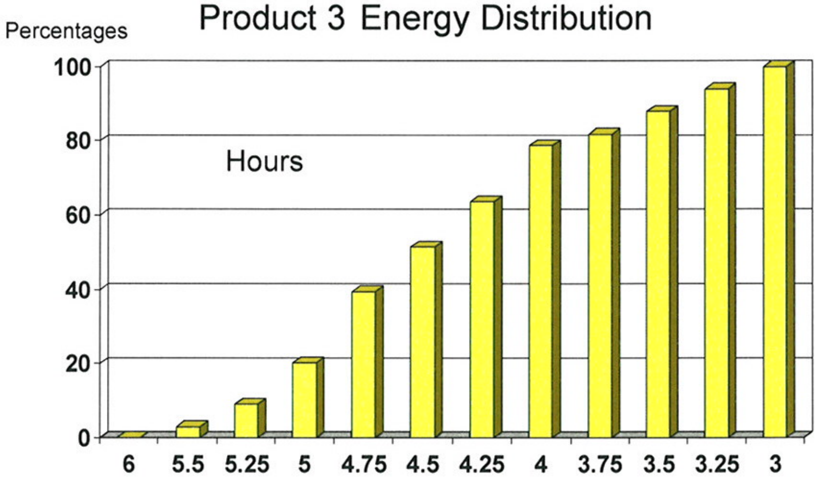
4.75
4.5
4.25
4
3.75
3.5
3.25
3

Energy Drink Clinical Trial Cumulative Distribution
Product 3 Energy Distribution


Percentages
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Hours
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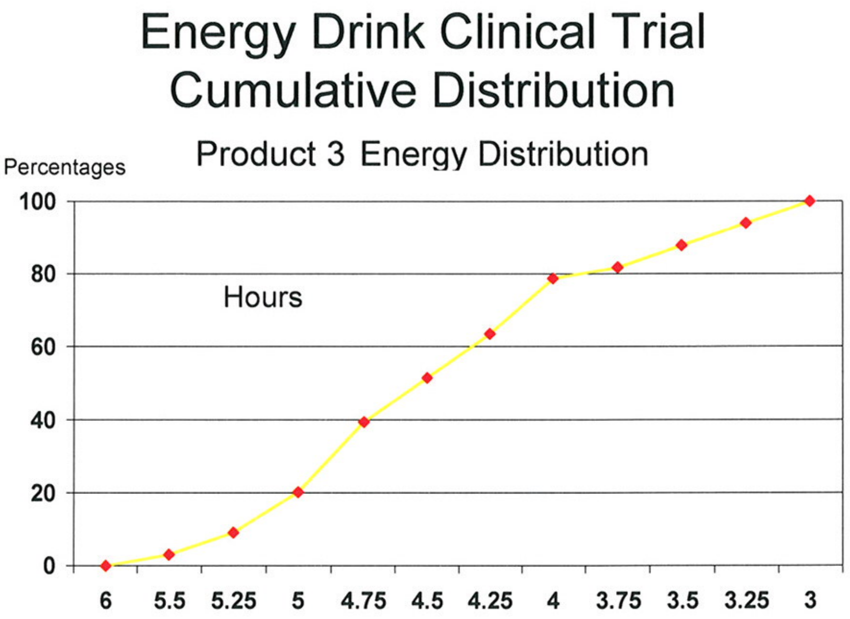
3


Energy Drink Clinical Trial
Cumulative Distribution
Product 3 Energy Distribution
Percentages
100
80
60
40
20
0
Hours
6
5.5
5.25
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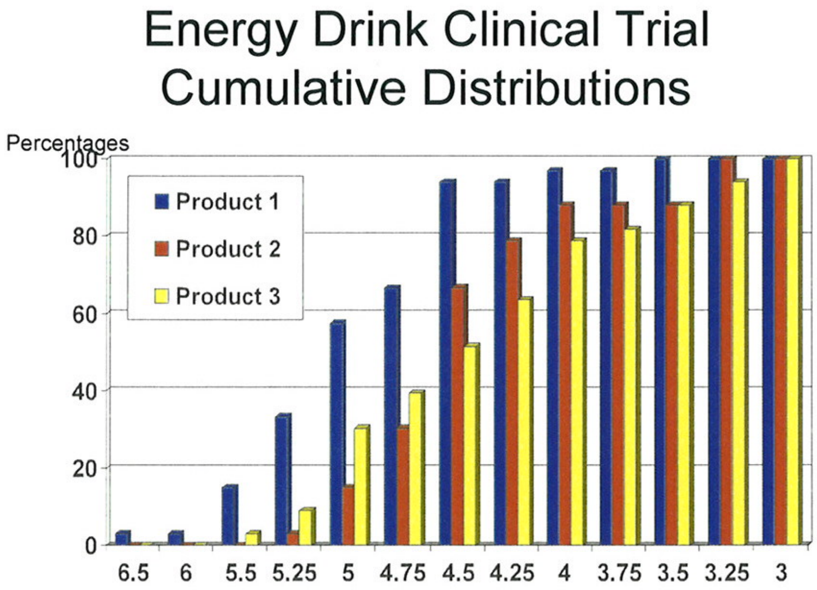
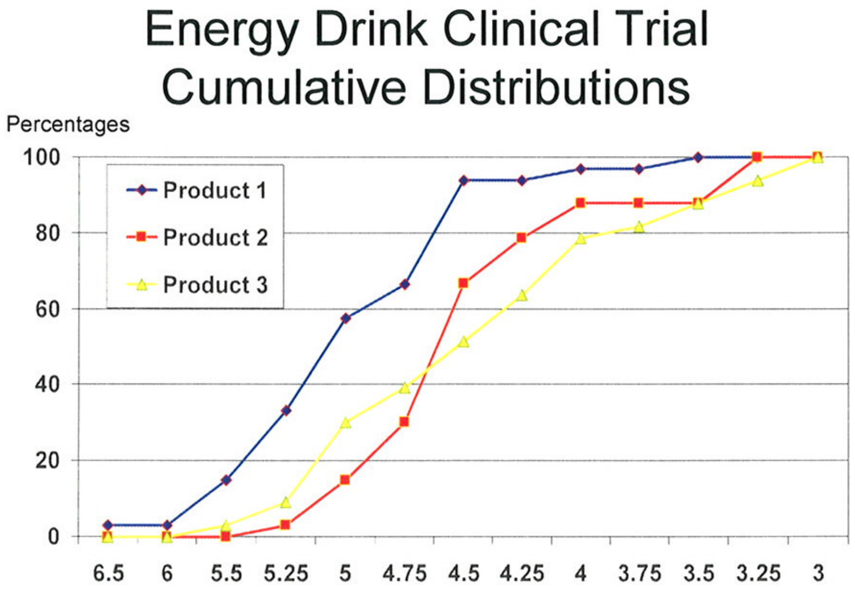
4.75
4.5
4.25
4
3.75
3.5
3.25
3

Comparing the Cumulative Distributions:


Energy Drink Clinical Trial
Cumulative Distributions
Percentages
100
80
60
40
20
0
Product 1
Product 2
Product 3
6.5
6
5.5
5.25
5
4.75
4.5
4.25
4
3.75
3.5
3.25
3


Energy Drink Clinical Trial
Cumulative Distributions
Percentages
100
80
60
40
20
0
Product 1
Product 2
Product 3
6.5 6 5.5 5.25 5 4.75 4.5 4.25 4 3.75 3.5 3.25 3

In this 3-way line graph comparison, it is easier to observe that the Product 1 curve is shifted to the left, whereas the Product 2 and Product 3 are intertwined and are essentially the same performance. The interpretation that the Product 1 curve was shifted to the left means that more individuals taking Product 1 reported longer intervals of energy, than when they took the other products.

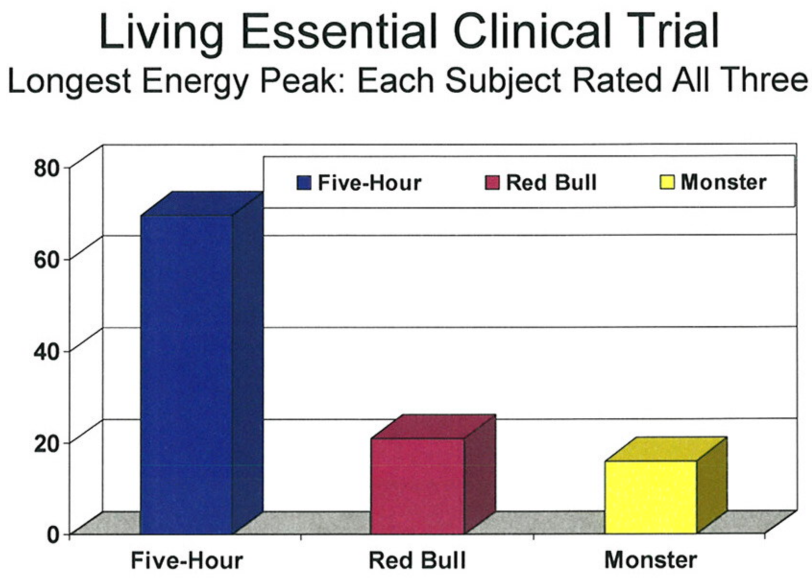
This graph shows that close to sixty percent of test subjects experienced five or more hours of energy from Product 1 versus thirty percent for Product 3 and twenty for Product 2. The study showed that ninety-four percent of test subjects had 4.5 or more hours of energy from Product 1 versus fifty-two percent for Product 3 and sixty-seven for Product 2.

Number of times for each beverage, a given individual named the specific drink the longest peak hours

5 – Hour	Product 2	Product 3
69.7%	21.2%	15.2%

Includes two ties between Product 1 and Product 3.

For this question, regardless of taste factors, individuals preferred Product 1 for the energy component approximately 3 to 1 over the other drinks.


Living Essential Clinical Trial
Longest Energy Peak: Each Subject Rated All Three
80
60
40
20
0
Five-Hour
Red Bull
Monster
Five-Hour
Red Bull
Monster

Crash Data

Mean and Range of Crash, as Defined as Following Peak (Hours)

This interval (time in hours) is measured from the peak (highest energy) until the point in time when the individual felt they had reached the low point of the day (the 'crash'). The shorter the time in this graph indicated that the person crashed in a shorter time period, while those with longer times had a more gradual slowing of their energy.

	Mean (hrs)	Std. Dev.	95% C.I Lower Limit	95% C.I. Upper Limit
Product 1	2.43	0.5	2.2	2.6
Product 2	1.36	0.4	1.2	1.5
Product 3	1.43	0.3	1.3	1.5

Notes on the Crash:

Nearly eighty percent (32/41) and three-quarters (29/40) of those taking Product 2 and Product 3 respectively, reported a Moderately-SEVERE crash that left them extremely tired and in need of rest, another drink, or some other action. Only twenty-four percent (10/42) of those taking Product 1 had similar reactions.

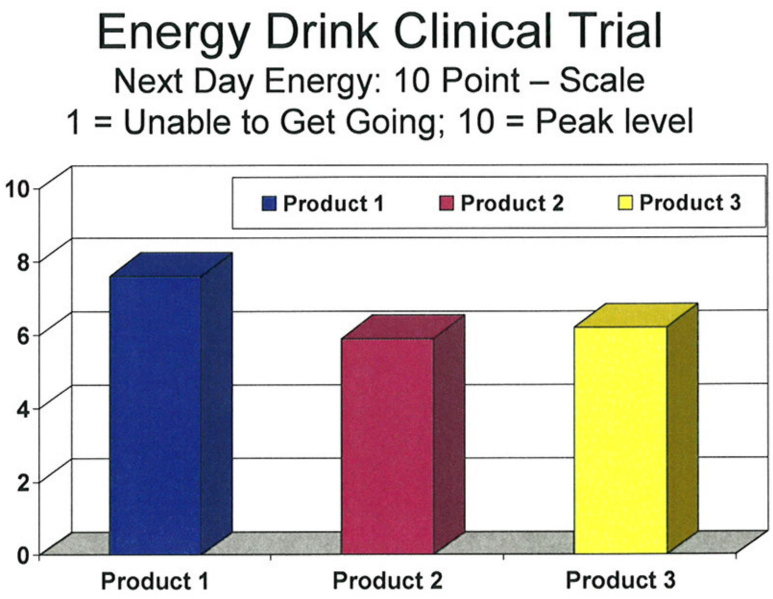
Next Day

How Do You Feel Today? (Asked by the research staff the following morning)

1 = Unable to get out of bed or get going

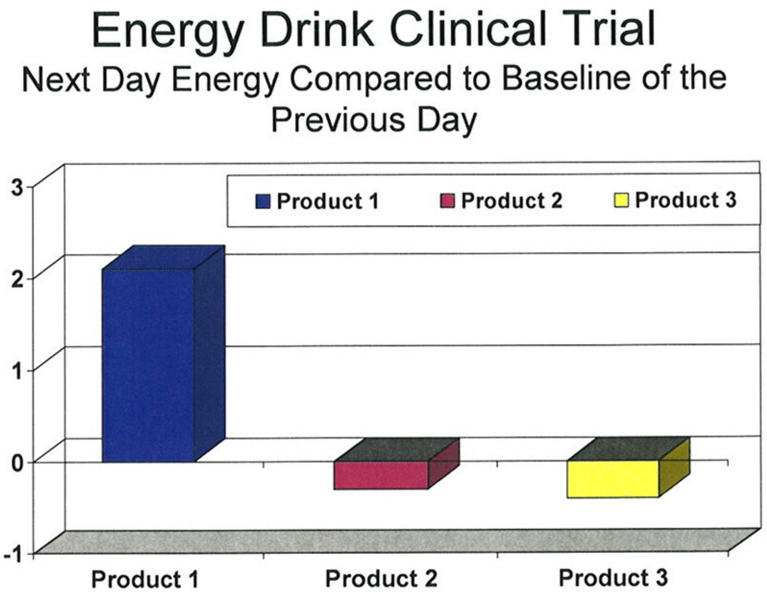
5 = Normal Level of Activity

10 = Peak Energy Level


Energy Drink Clinical Trial
Next Day Energy: 10 Point – Scale
1 = Unable to Get Going; 10 = Peak level
Product 1
Product 2
Product 3
10
8
6
4
2
0
Product 1
Product 2
Product 3

Next Day Energy

5 – Hour	Product 2	Product 3
7.6	5.9	6.2


Energy Drink Clinical Trial
Next Day Energy Compared to Baseline of the Previous Day
Product 1
Product 2
Product 3
3
2
1
0
-1
Product 1
Product 2
Product 3

Next Day Energy Compared to Baseline of the Previous Day

Product 1	Product 2	Product 3
2.1	- 0.3	- 0.4

A positive number indicates that individuals rated their energy HIGHER the following day as compared to the day of testing. A negative number signifies that the test subjects reported less energy the following day compared to the test day.

Thus, both subjects when testing Product 2 and Product 3, reported slightly less energy the following morning compared to the test day. Product 1 had higher energy the following day.

CONCLUSIONS:

In this randomized, product-controlled, double-blinded, cross-over clinical trial, three different 'energy' beverages were assessed using identical procedures. Subjects were screened based on Institutional-Review Board approved entrance criteria and underwent a placebo testing prior to testing each of the different energy beverages. The testing schedule was randomized meaning that each subject took the different beverages in random sequences.

All testing was done on a day-long basis requiring that each subject appear in the morning and afternoon. Subjects needed to be fully rested and had to allow a minimum of one day between testing days. Energy drinks were not permitted throughout the testing and alcoholic consumption was also prohibited. Every effort feasible was made to have unbiased testing of each different drink.

The baseline data for the cohort showed the following characteristics: sixty-three percent were males, which is not surprising but over a third of the group were women ensuring a mix of the genders. The average age was 27.4 with a standard deviation of 11 meaning that we had a full age range in this study and did not have an overabundance of twenty year old males. Eighteen percent of the group was of minority race also contributing to a healthy mix. The Body Mass Index was 26.8 +/- 5.5 indicating only a slightly overweight population. The group, on average, consumed two cups of caffeine drinks per day. This amount fits well within bounds of normal Americans and did not represent a group relying on high caffeine and large amounts of energy drinks. Actually sixty-one percent of the group had never had an energy beverage prior to the study and many indicated that this test offered a safe environment to assess them. Only eight percent normally consumed more than one energy drink a day on average.

The baseline lab data which included a complete metabolic profile, blood pressures, and pulse also were well within normal ranges. This provided assurance that none of the subjects had obvious metabolic disorders, and thus, was approved for testing.

An important conclusion is that this test population had few outliers with respect to their baseline data and most, if not all, of their behavioral tendencies fell within normal ranges.

Testing:

The data presented in this study was complete in that each subject tested all three beverages according to protocol.

With regards to the time frame associated with peak performance, Product 1 was the highest with a score of 4.92 hours, followed by Product 2 at 4.4 and Product 3 at 4.3 hours.

Nearly seventy percent of all subjects chose Product 1 as the best performer when it came to which beverage had the highest and longest effect. These two data points strongly indicate that Product 1 outperformed the other two beverages.

The crash or let-down data also supported Product 1 in that the subjects testing Product 1 had a more gentler let-down and did not go below their baseline, whereas the other drinks exhibited a crash that brought the energy of the subjects BELOW their morning energy level.

The actual peak levels achieved by each drink were comparable and no statistical differences were found.

There were several categories that did not show any differences between the drinks. These included the cognitive testing, metabolic rates, and exercise parameters.

In summary, for the primary end-points, Product 1 outperformed the other two beverages.

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Attorneys for Hansen Beverage Company

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

HANSEN BEVERAGE COMPANY, a Delaware corporation, Plaintiff, v. INNOVATION VENTURES+, LLC dba LIVING ESSENTIALS, a Michigan corporation, Defendant.	CASE NO. 08-CV-1166 IEG (POR) Assigned to The Hon. Irma Gonzalez **DECLARATION OF ANTHONY DONNELLY**

Anthony Donnelly declares:

1. The facts in this declaration are based on my personal knowledge.

2. I am a licensed private investigator in the State of Maine and a part-time employee of Corporate Intelligence, Inc. a licensed and accredited investigative services firm in Lewiston, Maine. Corporate Intelligence is licensed in both Maine and New Hampshire and is an accredited member of the national Association of legal Investigators.

3. Corporate Intelligence offers specialized services, among others, relating to litigation support, computer forensics (electronic discovery), forensic engineering (structural & civil), investigative surveillance, insurance fraud, security vulnerability assessment, computer security vulnerability assessment, background investigations (pre- and post-employment) and public information recovery.

4. On Thursday, September 4, 2008, I personally visited 344 Cumberland Street, Westbrook, Maine, a semi-rural suburb of Portland. It is the office of Maine Proctology Center of Richard Stockwell, D.O. I attach photographs I took that accurately depict what I observed.

5. I went inside the building at 344 Cumberland Street. From my personal observation, it appeared to be just a doctor's office. I personally spoke with the receptionist. She confirmed that it was the proctology practice of Dr. Stockwell. A person who appeared to be a patient sat in the waiting room.

6. Further research on Dr. Stockwell's practice states: "complete office-based proctology including painless hemorrhoid care, laser and infrared technology, minimally invasive office surgery, high resolution anoscopy, condyloma(warts), cancer screening and prevention and constipation/pelvic floor dysfunction. In Business Since 1998."

7. Beneath the Maine Proctology Center name on Dr. Stockwell's sign are the words, "Southern Maine Research Center." From my personal observation of the interior of 344 Cumberland Street, I saw no evidence of a medical research facility.

8. Property records show that Richard Stockwell owns the 344 Cumberland Street property and that the prior owner was Ira Stockwell.

medical research facility.

8. Property records show that Richard Stockwell owns the 344 Cumberland Street property and that the prior owner was Ira Stockwell.

9. Corporate Intelligence's search found no record whatsoever of any "independent medical research center" called "Southern Maine Research Center." A Maine registry search on the business, including tax records, produced nothing that identified Southern Maine Research Center.

I declare on penalty of perjury under the laws of the United States of America that the facts in this declaration are true and correct of my personal knowledge and that I executed it on September 5, 2008.

Anthony Donnelly

CERTIFICATE OF SERVICE

I caused the **DECLARATION OF ANTHONLY DONNELLY** to be served in the following manner:

Electronic Mail Notice List

The following are those who are currently on the list to receive e-mail notices for this case.

Daniel T. Pascucci, Esq. (SBN 166780) Nathan R. Hamler, Esq. (SBN 227765) Mintz Levin Cohn Ferris Glovsky and Popeo PC 3580 Carmel Mountain Road, Suite 300 San Diego, CA 92130 Telephone: (858) 314-1510 Facsimile: (858) 314-1501 dpascucci@mintz.com nhamler@mintz.com Attorneys for Innovation Ventures LLC dba Living Essentials	Mark B. Mizrahi, Esq. (SBN 179384) Belasco Jacobs & Townsley, LLP 6100 Center Drive, Suite 630 Los Angeles, CA 90045 Telephone: (310) 743-1188 Facsimile: (310) 743-1189 mmizrahi@bjtlaw.com Attorneys for Innovation Ventures LLC dba Living Essentials
Mark A. Cantor, Esq. Mark Lorelli, Esq. Thomas W. Cunningham, Esq. Brooks Kushman P.C. 1000 Town Center, 22d Floor Southfield, MI 48075 Telephone: (248) 358-4400 Facsimile: (248) 358-3351 mcantor@brookskushman.com mlorelli@brookskushman.com tcunningham@brookskushman.com Attorneys for Innovation Ventures LLC dba Living Essentials	

Manual Notice List

The following is the list of attorneys who are not on the list to receive e–mail notices for this case (who therefore require manual noticing).

None.

/s/ Edward J. McIntyre
EDWARD J. MCINTYRE

344
CUMBERLAND STREET
MPC
Maine
Proctology
Center
RICHARD STOCKWELL, D.O.
Southern Maine
RESEARCH CENTER

Exhibit 1, Page1

Maine
Proctology
Center

Exhibit 1, Page2

Exhibit 1, Page3